DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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BUFFALO DISTRICT
Food and Drug Administration
599 Delaware Avenue
Buffalo, NY 14202

10 February 1997

WARNING LETTER BUF 97-11

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Wayne Bacon, President
Mills Welding Supply, Inc.
85 Great Arrow Avenue
Buffalo, NY 14216

Dear Mr. Bacon:

Inspection of your medical gas repacking facility, CS Gases, Inc., 1811 Broadway Avenue, Buffalo, NY 14212, was performed 23 January 1997 by Food and Drug Administration Investigator Perry T. Nichols and Team Leader William J. Thompson. The inspection revealed Oxygen U.S.P. repacked at your facility is adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act) because the controls used for its manufacture, processing, packing or holding are not in conformance with current good manufacturing practice (CGMP) regulations.

The inspection revealed deviations from the CGMP regulations (Title 21, Code of Federal Regulations, Parts 210 and 211). An FDA-483 Inspectional Observations (copy enclosed) was issued to David D. Shiffler, Plant Manager, at the conclusion of the inspection. Deviations include the following:

-A valid certificate of analysis for incoming bulk shipments of oxygen is not obtained "or" in lieu of a valid certificate of analysis, full compendial testing per the United States Pharmacopeia would be required but is not conducted [21 CFR 211.84(d)(2)]; your bulk oxygen receipt documentation does not reflect the purity of the oxygen received on a lot by lot basis and if a valid certificate of analysis is not received, full compendial testing on the incoming oxygen would be required.

- No documentation indicating the [redacted] oxygen analyzer was calibrated at suitable intervals [21 CFR 211.160(b)(4)]; your "Equipment Calibration Log" for the [redacted] oxygen analyzer listed the last calibration date for the instrument as 17 April 1995.

- **The reliability of the testing by the supplier of bulk oxygen to your firm has not been established [211.84(d)(2)];** an acceptable method of establishing the reliability of oxygen testing by the supplier is by an on-site visit to the supplier by an employee trained in the analytical methodology to witness the test and documenting the visit. The above is a requirement when relying on a valid certificate of analysis for your receipt of bulk oxygen.

You should take prompt action to correct these violations and establish procedures whereby such violations will not recur. Failure to take prompt corrections may result in regulatory action **without further notice.** This may include seizure and/or injunction.

Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so they may take this information into account when considering contracts. By copy of this letter, we are specifically advising the Health Care Financing Administration (HCFA) that our inspection of your firm revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of State and Federal law.

If, after reviewing this Warning Letter and the COMPRESSED MEDICAL GASES GUIDELINE (copy attached), you still have questions regarding acceptable methods for complying with these requirements, you may contact William J. Thompson at the above address.

Please notify this office in writing, within fifteen days, of the specific steps you have taken to correct the noted violations and to prevent a recurrence of similar violations. Your response should be directed to William J. Thompson, Team Leader, at the above address.

Sincerely,

Irving Weitzman

Irving Weitzman
Acting District Director

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Attachments: -Compressed Medical Gases Guideline
-Fresh Air '96 - A Look At FDA's Medical Gas Requirements
-Copy FDA-483 Inspectional Observations

cc: David D. Shiffler, Plant Manager
CS Gases, Inc.
1811 Broadway Ave.
Buffalo, NY 14212

bcc: HFD-320 (D. Sylvia)
HFC-210 (1313065)
HFC-240
HFI-35 (redacted)
HFR-NE1
COMSTAT (TJB)
Legal File
EI File
NWB-RP
HCFA (W. Toby, Jr.)

T3 #97-1022